

### **REMARKS/ARGUMENTS**

Claims 70, 72, 73 to 82, 88 to 96, 102, 104, 105, 107 to 115, 121 to 136, 138, 139 and 141 to 175 remain in this application. Claims 71, 83 to 87, 97 to 101, 103, 106, 116 to 120, 137 and 140 have been canceled without prejudice to subsequent revival. Claims 156 to 175 have been added. Certain claims have been amended for the purpose of advancing the case toward allowance and differences between the presently pending claims and the claims as filed should not be viewed as acquiescence to any of the Examiner's rejections.

The presently amended specification and the presently amended claims and new claims are believed to include no new matter. The phrases "heterologous polypeptide," "a protein of pharmaceutical interest" and "fragment" have been introduced in the claims. Production of heterologous polypeptides is disclosed, for example, at page 3, line 18. The meaning of the phrase "a protein of pharmaceutical interest" is made clear based on the specification, for example, at page 2, line 3 to line 6. The meaning of the term fragment is made clear based on the specification, for example, at page 17, line 20 to page 18, line 5.

Applicant has amended Fig. 1 to specify one of Fig. 1a, Fig. 1b, Fig. 1c and Fig. 1d, for each of the four sheets of Fig. 1. Fig. 3 has been amended to specify one of Fig. 3a, Fig. 3b, Fig. 3c and Fig. 3d, for each of the four sheets of Fig. 3. Fig. 5 has been amended to specify one of Fig. 5a, Fig. 5b, Fig. 5c and Fig. 5d for each of the four sheets of Fig. 5.

In the Examiner's communication, the Examiner objects to certain claims. Applicant traverses the rejection. However, applicant believes that each of the Examiner's objections has been obviated by amendments applicant has made to the claims.

The Examiner rejects certain claims under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant traverses the rejection. However, applicant believes that the presently amended claims obviate the Examiner's rejections.

The Examiner rejects claims 70 to 87 under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The Examiner states that the claims as written are directed to a genus of DNA molecules wherein the lysozyme gene expression controlling region is necessarily linked to a heterologous coding sequence encoding chicken polypeptides other than chicken lysozyme. Examiner also rejects claims 70, 71, 75 to 103, 106 to 137 and 140 as failing to comply with the written description requirement stating that certain of the rejected claims relate to any variant of a lysozyme gene expression controlling region. Applicant traverses these rejections. However, applicant believes that the rejections are obviated by amendments made to the claims to more clearly present the invention.

The Examiner also indicates that for certain claims the degree of relationship between the lysozyme gene expressing controlling region and the embodiment disclosed in the specification is not limiting to any extent. Applicant believes that the Examiner is indicating

that the gene expression controlling region nucleotide sequence should be specified in the claims as being of a chicken species.

Applicant traverses this rejection. However, the presently pending claims have been amended to include claims for gene expression controlling regions which have at least 95% identity to SEQ ID NO: 67. One of ordinary skill in the art would expect that a nucleotide sequence comprising a sequence 95% identical to the sequence disclosed in SEQ ID NO: 67 would be operable as a chicken lysozyme gene expression controlling region.

The Examiner also states that there is a lack of guidance regarding the embodiments comprising less than 75% identity to SEQ ID NO: 67 and a skilled artisan would not be able to envision a sufficient number of specific embodiments to describe the broadly claimed genus of gene expression control regions. Applicant believes that in this rejection the Examiner is addressing applicants claims directed to functional portions or fragments of a lysozyme promoter. Applicant traverses the rejection.

As noted by the Examiner, the specification of the present application provides guidance as to potential regulatory elements located within SEQ ID NO: 67 (See, for example, Table II of Example 4). In addition, a practitioner of ordinary skill in the art would be expected to be able to carry out assays designed to identify fragments of SEQ ID NO: 67 which function as gene expression controlling regions. For example, Example 5 of the specification discloses the detection of heterologous protein expressed in quail oviduct cells by a functional lysozyme promoter. A practitioner of ordinary skill could use this method to identify functional fragments of SEQ ID NO: 67. Also, for example, as noted by the Examiner, Stief et al teach a series of reporter constructs comprising various elements of the chicken lysozyme gene expression controlling region operatively linked to a chloramphenicol acetyl transferase coding sequence (CAT). The constructs directed expression of the operatively linked CAT sequence in HD11/HBC1 cells upon transfection and integration of the constructs into the cells. Therefore, Stief et al identify exemplary functional fragments of the lysozyme gene expression controlling region and a method to identify more such functional fragments. Therefore, applicant submits that appropriate written description is provided and requests that the present rejection be withdrawn.

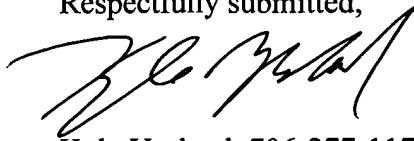
The Examiner rejects certain claims under 35 USC 102(b) as being anticipated by Stief et al. The Examiner states that Stief et al teach a series of reporter constructs comprising various elements of the chicken lysozyme promoter operatively linked to a chloramphenicol acetyl transferase coding sequence (CAT).

Applicant traverses the rejection. The currently pending claims are not limited to the nucleotide sequences disclosed in Stief et al. For example, a nucleotide sequence 95% identical to SEQ ID NO: 67 is not disclosed in Stief et al. In addition, nucleotide sequences at least 95% identical to a fragment of SEQ ID NO: 67 which function as a gene expression controlling region, as found in claim 74, include the feature of being operably linked to a nucleotide sequence encoding a protein of pharmaceutical interest and as such are distinguished from Stief et al. Therefore, applicant submits that Stief et al do not anticipate the presently pending claims and requests that the rejection be withdrawn.

In conclusion, applicant has shown that the present claims satisfy the requirements of 35 USC 112, first and second paragraphs and are not anticipated under 35 USC 102. Therefore, applicant submits that the presently pending claims are allowable and respectfully requests that the Examiner pass the above-identified application to allowance.

If any issues remain to be addressed in this matter, which might be resolved by discussion, the Examiner is respectfully requested to call applicants' undersigned counsel at the number indicated below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Kyle Yesland', written over the typed name.

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